

Terrestrial Animal Health Standards Commission Report September 2016

CHAPTER 4.11.

SOMATIC CELL NUCLEAR TRANSFER IN PRODUCTION LIVESTOCK AND HORSES

[Article 4.11.1.]

[...]

Article 4.11.4.

Background: risk analysis – general principles

- 1) *Risk analysis* in general includes *hazard* identification, *risk assessment*, *risk management* and *risk communication*. The *risk assessment* is the component of the analysis that estimates the *risks* associated with a *hazard* (see Chapter 2.1.). These principles are routinely used by regulators in making decisions about experimental or commercial releases. These analyses can then be used to determine whether the outcomes require management or regulation. *Risk management* is the process by which *risk* managers evaluate alternative actions or policies in response to the result(s) of the *risk assessment* taking into consideration the various social, economic, and legal considerations that form the environment in which such activities occur.
- 2) For animal *diseases*, particularly those listed in the *Terrestrial Code*, there is broad agreement concerning the likely *risks* and *risks assessments* can be qualitative or quantitative (see Chapter 2.1.). In *disease* scenarios it is more likely that a *qualitative risk assessment, in which the outputs on the likelihood of the outcome or the magnitude of the consequences are expressed in qualitative terms such as 'high', 'medium', 'low' or 'negligible'*, is all that is required. *Qualitative assessments* do not require mathematical modelling to carry out routine decision-making. *Quantitative risk assessments or semi-quantitative risk assessments* assign magnitudes to the *risks* in numerical *terms* (e.g. 1/1,000,000) or descriptive (high/medium/low) terms.
- 3) In the context of animal cloning, two broad categories of *risk assessments* are considered: absolute *risk assessment* and comparative *risk assessments*. Absolute *risk assessments* characterise *risk* independent of a comparator (e.g. the likelihood of an animal transmitting a specific livestock *disease*). A comparative *risk assessment* (or relative *risk assessment*) puts the *risk* in the context of a comparator. For example the degree to which an animal produced by one reproductive technology can transmit a particular *disease* to another animal of the same species compared with the degree to which a similar animal produced by another reproductive technology transmits the same *disease* to another animal of same species.
- 4) Regardless of the methodology used, *hazard* identification is an early step in all science-based *risk assessments*. In the context of assessing the *risks* associated with animal cloning (SCNT) and starting with the embryo and moving on through animal clone development and subsequent progeny, it is important to be clear at this juncture that only a comparative *semi-quantitative risk assessment* can be completed. A systematic, absolute, *quantitative risk assessment* of potential *risks* is difficult, due to the relative newness of the technology, and the variability in outcomes among laboratories and species cloned. Furthermore, with the technology of SCNT there is no introduced *hazard* from the insertion of novel genes (which may potentially happen in transgenesis). Thus, to analyse what factors contribute to animal health *risks*, the existing baseline must be analysed.
- 5) In short, the specific points where the *risk assessment* needs to be focused need to be identified. As illustrated in the accompanying diagram – the focus is to look at the basics of creating an embryo – using current terminology, starting from the selection of donor of oocyte and the cells to the creation of an embryo by the cloning methodology. The second phase will focus on the recipient of the embryo clone and the animal health and care considerations for the animals. The actual embryo clone that is born as an offspring is the third part of the paradigm that needs clear recommendations for assessment, and the next generation, either the progeny of the animal clone (which is a result of normal sexual reproduction) or animals produced by re-cloning (clones of clones) is the fourth and final stage.

[Article 4.11.5.]

[...]

[Article 4.11.7.]

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